# ThermoChem™ HT-2000 System

## Traditional 510(k) Summary

**Submitted by:** ThermaSolutions, Inc.
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OCT 0 3 2013

**Date of Summary:** 29 September 2013

**Device Trade Name:** ThermoChem™ HT-2000 System and Intraperitoneal Hyperthermia (IPH) Procedure Kit

**Common or Usual Name:** Warmer, Peritoneal Dialysate

**Classification:** 876.5630

**Product Code:** MLW

**Predicate Device(s)** ThermoChem HT-1000 System, K993330

**Device Description:**

The ThermoChem HT-2000 System is a next-generation design of the currently marketed ThermoChem HT-1000 System and consists of the ThermoChem unit, a touchscreen monitor and an Intraperitoneal Hyperthermia (IPH) Procedure Kit, or "Disposable."

The ThermoChem unit houses an internal heating unit that warms distilled or sterile water to a desired temperature. This water is circulated around a single-use heat exchanger (included in the IPH Procedure Kit) where it warms Lactated Ringer's (or another physiologically compatible sterile solution) for infusion into the patient's peritoneal cavity.

The IPH Procedure Kit contains two temperature probes, two suction guards, and a pressure sensor as well as a Perfusion Kit consisting of a heat exchanger, a fluid reservoir, and tubing set. The warmed Lactated Ringer's (or other physiologically compatible sterile solution) is pumped through the tubing to the patient and then returns to the fluid reservoir. The IPH Procedure Kit is a convenience kit of previously 510(k)-cleared devices that are repackaged / relabeled by ThermaSolutions, Inc.

The ThermoChem HT-2000 unit has been redesigned to physically reduce the size of the unit and to allow use of components that are more commercially available. The software and touchscreen monitor user interface have been redesigned to make the device easier to use. The redesigned ThermoChem unit will continue to use the currently-marketed IPH Procedure Kit for use with the ThermoChem HT-1000 System.

**Intended Use:**

The intended use of the ThermoChem™ HT-2000 System is to raise the core temperature of the peritoneum to a desired target temperature by continuously lavaging the peritoneum with circulating and warmed Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution.

**Technological Characteristics:**

The ThermoChem HT-2000 is a next-generation design of the currently-marketed ThermoChem HT-1000 system intended to integrate more-commercially-available components and incorporate changes to make the device easier to use, including a more user-friendly graphical user interface. In addition, the software was upgraded to incorporate currently-supported operating systems (QNX) and drivers. There was no change to the essential mode of operation of the device.

**Performance Testing** The ThermoChem HT-2000 System underwent and met acceptance criteria of formal verification testing including bench testing of pump settings (pressure, flow rate); water bath heat time and temperatures; operating conditions; fluid ingress, overfill, and spill tests; software validation and regression testing; and usability validation testing.

**Substantial Equivalence:** Based on device specifications and test results, the ThermoChem HT-2000 can be considered to be substantially equivalent to its predicate device, the ThermoChem HT-1000 system. Both devices share the same intended use and incorporate the same technological characteristics. Both devices are intended to be used with the ThermoChem IPH Procedure Kit. The ThermoChem HT-2000 is a next-generation design of the currently-cleared ThermoChem HT-1000 system intended to integrate more-commercially-available components and incorporate changes to make the device easier to use, including a more user-friendly graphical user interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

ThermaSolutions, Inc.
% M.W. (Andy) Anderson, Ph.D., RAC
Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc. (RCRI)
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416

Re: K131583
Trade/Device Name: ThermoChem™ HT-2000 System and
Intraperitoneal Hyperthermia (IPH) Procedure Kit
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: MLW
Dated: August 21, 2013
Received: August 22, 2013

Dear M.W. (Andy) Anderson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

**510(k) Number:** K131583

**Device Name:** ThermoChem™ HT-2000 System and Intraperitoneal Hyperthermia (IPH) Procedure Kit

**Intended Use:** The intended use of the ThermoChem™ HT-2000 System is to raise the core temperature of the peritoneum to a desired target temperature by continuously lavaging the peritoneum with circulating and warmed Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution.

Prescription Use: **YES** AND/OR Over-the-Counter Use: **NO**

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Herbert P. Lerner -S
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